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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,670	08/15/2005	Gregory Raymond Bebernitz	PC/4-32711A	8433

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EXAMINER	
STOCKTON, LAURA LYNNE	
ART UNIT	PAPER NUMBER
1626	
MAIL DATE	DELIVERY MODE
04/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,670	BEBERNITZ, GREGORY RAYMOND	
	Examiner	Art Unit	
	Laura L. Stockton	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-7,12-18 and 25* is/are pending in the application.

4a) Of the above claim(s) *12-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-7, 16-18 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

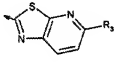
Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *January 22, 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 4-7, 12-18 and 25 are pending in the application.

Election/Restrictions

Applicant's election of Group III (claims 1, 4-7, 16-18 and 24 drawn to products of formula (I) wherein Q is ) in the reply filed on May 22, 2008 was acknowledged in the previous Office Action. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement was deemed proper and therefore made FINAL in the previous Office Action.

Subject matter not embraced by elected Group III and Claims 2, 3 and 8-15 are withdrawn from further

consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 22, 2008.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statement filed on January 22, 2009.

Rejections made in the previous Office Action that do not appear below have been overcome by Applicant's amendments to the claims. Therefore, arguments pertaining to these rejections will not be addressed.

Claim Objections

Claims 1 and 18 are objected to because of the following informalities:

a) in claim 1, last line of claim, the first "or" should be deleted since an "or" is present after the second definition of variable R; and

b) in claim 18, "pharmaceutical" is misspelled.

Appropriate correction is required.

Claim 18 was inadvertently not included in the 35 USC 112, first paragraph, rejection. Therefore, the following applies.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement

requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

Applicant is claiming a pharmaceutical composition comprising a compound of formula (I) for the treatment of impaired glucose tolerance, Type 2 diabetes and obesity. See instant claim 24. From the reading of the specification (page 28), "treatment" is defined as follows

As used throughout the specification and in the claims, the term "treatment" embraces all the different forms or modes of treatment as known to those of the pertinent art and in particular includes preventive, curative, delay of progression and palliative treatment.

The state of the prior art and the predictability or lack thereof in the art

The state of the art is that the prevention of diabetes remains highly unpredictable. Colagiuri et al. {American Journal of Public Health, September 2006, Vol. 96, No. 9, pages 1562-1569} state "Type 2 diabetes is a complex metabolic disorder triggered by lifestyle factors superimposed on a genetic predisposition." Colagiuri et al. also state "Although we recognize the benefits of science, surgery, and service delivery in relation to certain aspects of chronic disease

prevention, it is clear that, either independently or in concert, none can achieve the broad scale changes required to prevent diabetes and obesity on a population basis."

According to Bruno et al. {Expert Opinion Emerging Drugs, (2005), 10(4), pages 747-771}, diabetes mellitus is a major health problem that affects over 170 million people worldwide. Park {Diabetes Research and Clinical Practice 66S (2004), S33-S35} states current methods of treating diabetes is inadequate and that current strategies to prevent type 2 diabetes mellitus are based on efforts to reduce insulin resistance and to preserve or increase pancreatic beta cell function in high risk individuals. Park also states, "It appears that multiple genes with weak effect are involved in the development of type 2 diabetes mellitus which makes searching diabetogenic genes more complicated." Curtis et al. {The Journal of the American Board of Family Practice, Vol. 18, pages 37-43, (2005)} state "there is

much yet to learn about preventing type 2 diabetes". From Curtis et al., it is clear that there are currently no medications on the market that has been successful in the prevention of diabetes.

The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present and the presence or absence of working examples

There is no evidence of record which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the diseases claimed in the pharmaceutical compositions. That a single class of compounds can be used to prevent or cure the diseases stated in the claims is an incredible finding for which Applicant has not provided persuasive supporting evidence.

The breadth of the claims

The breadth of the claims is a pharmaceutical composition for impaired glucose tolerance, Type 2 diabetes and obesity.

The quantity of experimentation needed

The nature of the pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities for each of the diseases instantly claimed in the composition. The quantity of experimentation needed would be undue when faced with the lack of testing, and when faced with the unpredictability of the pharmaceutical art. Thus, factors such as "sufficient working examples", "the level of skill in the art" and predictability, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

The level of the skill in the art

Even though the level of skill in the pharmaceutical art is very high, based on the unpredictable nature of the invention and state of the prior art, one skilled in the art could not use the claimed invention without undue experimentation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-7, 16-18 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9, 16-20, 27, 32, 37 and 39 of copending Application No. 11/547,046; over claims 1-14, 19 and 21 of copending Application No. 11/547,227; over claims 1, 23, 25 and 32 of copending Application No. 12/088,594; and over claims 1, 2, 13, 16, 17, 21, 27, 29, 36 and 37 of copending Application No. 12/088,608. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed invention is generically claimed in each of the aforementioned copending applications.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (C.C.P.A. 1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., anti—obesity agent).

One skilled in the art would thus be motivated to prepare products embraced by the copending applications to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, obesity. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed January 22, 2009 have been fully considered. Applicant argues that the presently pending claims have an earlier filing date than the above cited co-pending applications. Applicant further argues that the present claims are not obvious over the copending later filed applications.

In response, it is disagreed that the instant claimed invention is not obvious over the above cited copending applications. See, for example, claim 28 in copending application 11/547,046. The rejection is deemed proper and therefore, the rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on

(571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton/
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April 27, 2009